



[Billing Code 4140-01-P]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

42 CFR Part 11

[Docket Number NIH-2011-0003]

RIN: 0925-AA52

Clinical Trials Registration and Results Submission

AGENCY: National Institutes of Health, Department of Health and Human Services.

ACTION: Proposed rule; extension of comment period; request for comments.

SUMMARY: The Department of Health and Human Services (HHS) is extending the public comment period for the Notice of Proposed Rulemaking (NPRM) on Clinical Trials Registration and Results Submission. The proposed rule was published on November 21, 2014 (79 FR 69566) with a deadline for public comments of February 19, 2015. The comment period is being extended to provide additional time for commenters to prepare their responses. The comment period will close at 5pm Eastern Standard Time (EST) on March 23, 2015.

DATES: Comments on the NPRM must be received before 5pm EST on March 23, 2015 in order to ensure we will be able to consider the comments when preparing the final rule and policy.

ADDRESSES: Individuals and organizations interested in submitting comments on the NPRM, identified by RIN 0925-AA52 and Docket Number NIH-2011- 0003, may do so by any of the following methods:

- Electronic Submissions: Use Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. NIH is no longer accepting comments submitted directly by email. The NIH encourages you to continue to submit electronic comments by using the Federal eRulemaking Portal: <http://www.regulations.gov>.
- Written Submissions: You may submit written submissions by Fax at 301-402-0169, or by Mail/Hand Delivery/Courier (For paper, disk, or CD-ROM submissions) to: Jerry Moore, NIH Regulations Officer, Office of Management Assessment, 6011 Executive Boulevard, Suite 601, MSC 7669, Rockville, MD 20852-7669.

FOR FURTHER INFORMATION CONTACT:

Regulatory Process: Jerry Moore, NIH Regulations Officer, Office of Management Assessment, Telephone (301-496-4607) (not a toll-free number), Fax (301-402-0169), or by email at jm40z@nih.gov.

Technical Information: Jerry Sheehan, Assistant Director for Policy Development, National Library of Medicine, National Institutes of Health, Department of Health and Human Services, Telephone (301-496-6221) (not a toll-free number), Fax (301-402-2586), or by email at sheehanjr@nlm.nih.gov.

SUPPLEMENTARY INFORMATION: HHS published a Notice of Proposed Rulemaking (NPRM) on Clinical Trials Registration and Results Submission in the Federal Register on November 21, 2014 (79 FR 69566). The NPRM proposes requirements for submitting registration and summary results information, including adverse event information, for specified clinical trials of drugs (including biological

products) and devices and for pediatric postmarket surveillances of a device to ClinicalTrials.gov, the clinical trial registry and results data bank operated by the National Library of Medicine. The proposed rule provides for the expanded registry and results data bank specified in Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) to enhance patient enrollment, provide a mechanism to track subsequent progress of clinical trials, provide more complete results information, and enhance patient access to and understanding of the results of clinical trials. The deadline for written comments was originally established as February 19, 2015. Since the NPRM was published, the Department has received requests to extend the period for the public submission of comments. Effective with this notice, we are extending the comment period with a deadline of 5pm EST on March 23, 2015.

NIH published a related request for public comments on a draft NIH Policy on Dissemination of NIH-Funded Clinical Trial Information in the NIH Guide for Contracts and Grants (NOT-OD-15-019) on November 19, 2014. See <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-019.html>. The draft NIH Policy aims to promote broad and responsible dissemination of information on clinical trials funded by the NIH through registration and submission of summary results information to ClinicalTrials.gov. The original deadline for written comments on the draft NIH Policy was February 19, 2015, but the deadline is also being extended until 5pm EST on March 23, 2015.

Instructions for Submitting Comments: We welcome comments from the public on all issues set forth in the proposed rule, and on specific issues identified in the document. All

submissions received must include the agency name, the Docket No., and Regulatory Information Number (RIN) for this rulemaking. All comments received at <http://www.regulations.gov> may be posted without change, including any personal information provided. The <http://www.regulations.gov> Web site is an “anonymous access” system, which means NIH will not know your identity or contact information unless you provide it in the body of your comment. You can assist us in considering your comment by referencing the number assigned to each key issue discussed in section III.C of the preamble or the number of the section of this proposed rule to which your comment relates. For access to background documents or comments received, go to <http://www.regulations.gov> and insert the docket number found in the brackets in the heading of this document into the “Search” box and follow the prompts.

Dated: January 16, 2015.

Approved: February 5, 2015.

Francis S. Collins

Director, National Institutes of Health

Sylvia Mathews Burwell

Secretary, HHS

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